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March 16, 2007

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Art Unit 1618

Attn: Mail Stop Amendment

Re: U.S. Utility Patent Application
Application No. 10/565,885; Filed: January 25, 2006
For: **Administration of Anti-Cytokine F(ab')₂ Antibody Fragments**
Inventors: LOPEZ DE SILANES *et al.*
Our Ref: 2399.0080000/JAG/LAV

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement Under 37 C.F.R. § 1.97(b);
2. Form PTO/SB/08A (1 sheet) listing twenty-three (23) documents (US1-US20 and FP1-FP3);
3. Form PTO/SB/08B (4 sheets) listing thirty-five (35) documents (NPL1-NPL35);
4. Copies of thirty-eight (38) cited documents (FP1-FP3 and NPL1-NPL35); and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents

March 16, 2007

Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink that reads "Laura Vogel". The signature is written in a cursive, flowing style.

Laura A. Vogel
Attorney for Applicants
Registration No. 55,702

LAV/U-W:trh:amr
Enclosures

652662_1.DOC



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

LOPEZ DE SILANES *et al.*

Appl. No.: 10/565,885

Filed: January 25, 2006

For: **Administration of Anti-Cytokine
F(ab')₂ Antibody Fragments**

Confirmation No.: 8053

Art Unit: 1618

Examiner: *To Be Assigned*

Atty. Docket: 2399.0080000/JAG/LAV

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Mail Stop Amendment

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms, PTO/SB/08A and PTO/SB/08B, are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **FP1** to **FP3** and **NPL1** to **NPL35** are submitted herewith. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, **US1** to **US20**, cited on the attached IDS Form, PTO/SB/08A, are not submitted.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language document **NPL18** cited on Form PTO/SB/08B:

Document **NPL18**, Maraboto Martinez, J.A., *et al.*, "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzofiosos en la Población Derechohabiente del IMSS 1990-1998," in *3^a Reunión de Expertos en Envenenamiento*

por Animales Ponzoñosos, Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999), is in the Spanish language. An English language translation of document NPL18 is attached as **NPL19**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

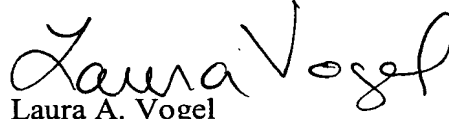
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

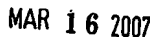


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Date: 3/16/07

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Substitution form 1449/PTO

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|------------------------|------------------------|
| Application Number | 10/565,885 |
| Filing Date | January 25, 2006 |
| First Named Inventor | LOPEZ DE SILANES, Juan |
| Art Unit | 1618 |
| Examiner Name | <i>To Be Assigned</i> |
| Attorney Docket Number | 2399.0080000/JAG/LAV |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (If Known) | | | |
| | US1 | 4,806,346 | 02/21/1989 | Hum <i>et al.</i> | |
| | US2 | 4,814,433 | 03/21/1989 | Fredrickson | |
| | US3 | 4,849,352 | 07/18/1989 | Sullivan <i>et al.</i> | |
| | US4 | 4,940,670 | 07/10/1990 | Rhodes | |
| | US5 | 5,328,834 | 07/12/1994 | Ngo <i>et al.</i> | |
| | US6 | 5,443,976 | 08/22/1995 | Carroll | |
| | US7 | 5,733,742 | 03/31/1998 | Landon | |
| | US8 | 5,888,511 | 03/30/1999 | Skurkovich <i>et al.</i> | |
| | US9 | 5,904,922 | 05/18/1999 | Carroll | |
| | US10 | 6,333,032 | 12/25/2001 | Skurkovich <i>et al.</i> | |
| | US11 | 6,448,054 | 09/10/2002 | Poznansky <i>et al.</i> | |
| | US12 | 6,534,059 | 03/18/2003 | Skurkovich <i>et al.</i> | |
| | US13 | 6,709,655 | 03/23/2004 | Lopez de Silanes <i>et al.</i> | |
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| | US15 | 2003/0215448 A1 | 11/20/2003 | Skurkovich <i>et al.</i> | |
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| | US17 | 2003/0224005 A1 | 12/04/2003 | Skurkovich <i>et al.</i> | |
| | US18 | 2003/0228310 A1 | 12/11/2003 | Skurkovich <i>et al.</i> | |
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| | US20 | 2004/0086508 A1 | 05/06/2004 | Skurkovich <i>et al.</i> | |

FOREIGN PATENT DOCUMENTS

[illegible]

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| Examiner Signature | | Date Considered | |
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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i> | | | | Complete if Known | |
| | | | | Application Number | 10/565,885 |
| | | | | Filing Date | January 25, 2006 |
| | | | | First Named Inventor | LOPEZ DE SILANES, Juan |
| | | | | Art Unit | 1618 |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 1 | of | 4 | Attorney Docket Number | 2399.0080000/JAG/LAV |

| NON PATENT LITERATURE DOCUMENTS | | | |
|--|-----------------------|--|----------------|
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T ² |
| | NPL1 | BECERRIL, B., <i>et al.</i> , "Cloning and characterization of cDNAs that code for Na ⁺ - channel-blocking toxins of the scorpion <i>Centruroides noxius</i> Hoffman," <i>Gene</i> 128:165-171, Elsevier Science Publishers B.V. (1993) | |
| | NPL2 | CAIN, B.S., <i>et al.</i> , "The Physiologic Basis for Anticytokine Clinical Trials in the Treatment of Sepsis," <i>J. Am. Coll. Surg.</i> 186:337-351, American College of Surgeons (1998) | |
| | NPL3 | CALDERON-ARANDA, E.S., <i>et al.</i> , "Neutralizing Capacity of Murine Sera Induced by Different Antigens of Scorpion Venom," <i>Toxicon</i> 31:327-337, Pergamon Press Ltd. (1993) | |
| | NPL4 | CALDERON-ARANDA, E.S., <i>et al.</i> , "The use of synthetic peptides can be a misleading approach to generate vaccines against scorpion toxins," <i>Vaccine</i> 13:1198-1206, Elsevier Science, Ltd. (1995) | |
| | NPL5 | COURAUD, F., <i>et al.</i> , "Two Types of Scorpion Toxin Receptor Sites, One Related to the Activation, the Other to the Inactivation of the Action Potential Sodium Channel," <i>Toxicon</i> 20:9-16, Pergamon Press Ltd. (1982) | |
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| | NPL7 | DEHESA-DÁVILA, M., <i>et al.</i> , "Clinical Toxicology of Scorpion Stings," in <i>Handbook of Clinical Toxicology of Animal Venoms and Poisons</i> , Ch. 18, Meier, J., and White, J., eds., CRC Press, Boca Raton, FL, pp. 221-238 (1995) | |
| | NPL8 | Abstract of DICK, A.D., <i>et al.</i> , "Neutralizing TNF-alpha Activity Modulates T-cell Phenotype and Function in Experimental Autoimmune Uveoretinitis," <i>J. Autoimmun.</i> 11:255-264 (1998) | |
| | NPL9 | EDMAN, P. and Begg, G., "A Protein Sequenator," <i>Eur. J. Biochem.</i> 1:80-91, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1967) | |
| | NPL10 | FEKADE, D., <i>et al.</i> , "Prevention of Jarisch-Herxheimer Reactions by Treatment with Antibodies Against Tumor Necrosis Factor α ," <i>N. Engl. J. Med.</i> 335:311-315, Massachusetts Medical Society (1996) | |

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| Examiner Signature | | Date Considered | |
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/565,885 |
| | | | | Filing Date | January 25, 2006 |
| | | | | First Named Inventor | LOPEZ DE SILANES, Juan |
| | | | | Art Unit | 1618 |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 2 | of | 4 | Attorney Docket Number | 2399.0080000/JAG/LAV |

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| | NPL11 | FOX, D.A., "Cytokine Blockade as a New Strategy to Treat Rheumatoid Arthritis," <i>Arch. Intern. Med.</i> 160:437-444, American Medical Association (2000) | |
| | NPL12 | GARCÍA, C., <i>et al.</i> , "Isolation, Characterization and Comparison of Novel Crustacean Toxin with a Mammalian Toxin from the Venom of the Scorpion <i>Centruroides noxius</i> Hoffman," <i>Comp. Biochem. Physiol.</i> 116B:315-322, Elsevier Science, Inc. (1997) | |
| | NPL13 | KRUEGER, J.G., "The immunologic basis for the treatment of psoriasis with new biologic agents," <i>J. Am. Acad. Dermatol.</i> 46:1-23, American Academy of Dermatology, Inc. (January 2002) | |
| | NPL14 | LEGROS, C., <i>et al.</i> , "Use of fusion protein constructs to generate potent immunotherapy and protection against scorpion toxins," <i>Vaccine</i> 20:934-942, Elsevier Science, Ltd. (2002) | |
| | NPL15 | LICEA, A.F., <i>et al.</i> , "FAB Fragments of the Monoclonal Antibody BCF2 are Capable of Neutralizing the Whole Venom from the Scorpion <i>Centruroides noxius</i> Hoffman," <i>Toxicon</i> 34:843-847, Elsevier Science Ltd. (1996) | |
| | NPL16 | LISMAN, K.A., <i>et al.</i> , "Managing Heart Failure with Immunomodulatory Agents," <i>Cardiol. Clin.</i> 19:617-625, W.B. Saunders Co. (2001) | |
| | NPL17 | LUGER, T., "Treatment of immune-mediated skin diseases: future perspectives," <i>Eur. J. Dermatol.</i> 11:343-347, accessed at http://www.john-libbey-eurotext.fr/en/revues/medecine/ejd/e-docs/00/01/88/A6/article.md , John Libbey Eurotext (2001) | |
| | NPL18 | MARABOTO MARTINEZ, J.A., <i>et al.</i> , "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzosos en la Población Derechohabiente del IMSS 1990-1998," in <i>3ª Reunión de Expertos en Envenenamiento por Animales Ponzosos</i> , Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999) | |
| | NPL19 | English translation of Maraboto Martinez, J.A., <i>et al.</i> , "Panorama Epidemiológico de las Intoxicaciones Causadas por Animales Ponzosos en la Población Derechohabiente del IMSS 1990-1998," in <i>3ª Reunión de Expertos en Envenenamiento por Animales Ponzosos</i> , Instituto de Biotecnología, Universidad Nacional Autónoma de México, Alcapulco, Gro., México (February 17-19, 1999) | |
| | NPL20 | MARTIN, G.S., "Current Management Strategies for Severe Sepsis and Septic Shock," Presented at Chest 2001: 67th Annual Scientific Assembly of the American College of Chest Physicians, November 4-8, 2001, Philadelphia, PA, accessed online at http://www.medscape.com/viewarticle/412927 , Medscape Portals, Inc., 4 pages (2001) | |

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| NON PATENT LITERATURE DOCUMENTS | | | |
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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T ² |
| | NPL21 | NONNER, W., "Effects of <i>Leiurus</i> Scorpion Venom on the "Gating" Current in Myelinated Nerve," <i>Adv. Cytopharmacol.</i> 3:345-352, Raven Press (1979) | |
| | NPL22 | POSSANI, L.D., <i>et al.</i> , "Scorpion toxins from <i>Centruroides noxius</i> and <i>Tityus serrulatus</i> ," <i>Biochem. J.</i> 229:739-750, Biochemical Society/Portland Press (1985) | |
| | NPL23 | POSSANI, L.D., <i>et al.</i> , "Scorpion toxins specific for NA ⁺ -channels," <i>Eur. J. Biochem.</i> 264:287-300, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1999) | |
| | NPL24 | POSSANI, L.D., <i>et al.</i> , "Peptides and genes coding for scorpion toxins that affect ion-channels," <i>Biochimie</i> 82:861-868, Editions Scientifiques Elsevier (2000) | |
| | NPL25 | PRESENT, D.H., <i>et al.</i> , "Infliximab for the Treatment of Fistulas in Patients with Crohn's Disease," <i>N. Engl. J. Med.</i> 340:1398-1405, Massachusetts Medical Society (1999) | |
| | NPL26 | QIAN, Y., <i>et al.</i> , "Topical Soluble Tumor Necrosis Factor Receptor Type I Suppresses Ocular Chemokine Gene Expression and Rejection of Allogenic Corneal Transplants," <i>Arch. Ophthalmol.</i> 118:1666-1671, American Medical Association (2000) | |
| | NPL27 | STAPCZYNSKI, J.S., "Shock, Septic," Dire, D.J., <i>et al.</i> , eds., eMedicine.com Inc., accessed online at http://emedicine.com/EMERG/topic533.htm , eMedicine.com, Inc., 25 pages (2004) | |
| | NPL28 | STRICHARTZ, G., <i>et al.</i> , "An Integrated View of the Molecular Toxinology of Sodium Channel Gating in Excitable Cells," <i>Ann. Rev. Neurosci.</i> 10:237-267, Annual Reviews, Inc. (1987) | |
| | NPL29 | TORRES, P.F., and KIJLSTRA, A., "The role of cytokines in corneal immunopathology," <i>Ocul. Immunol. Inflamm.</i> 9:9-24, Swets & Zeitlinger (2001) | |
| | NPL30 | ZAMUDIO, F., <i>et al.</i> , "Amino acid sequence and immunological characterization with monoclonal antibodies of two toxins from the venom of the scorpion <i>Centruroides noxius</i> Hoffman," <i>Eur. J. Biochem.</i> 204:281-292, Blackwell Science, Ltd. on behalf of the Federation of European Biochemical Societies (1992) | |

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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/565,885 |
| | | | | Filing Date | January 25, 2006 |
| | | | | First Named Inventor | LOPEZ DE SILANES, Juan |
| | | | | Art Unit | 1618 |
| | | | | Examiner Name | To Be Assigned |
| Sheet | 4 | of | 4 | Attorney Docket Number | 2399.0080000/JAG/LAV |

| NON PATENT LITERATURE DOCUMENTS | | | |
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| | NPL31 | ZHU, S., <i>et al.</i> , "Early Expression of Proinflammatory Cytokines Interleukin-1 and Tumor Necrosis Factor- α after Corneal Transplantation," <i>J. Interferon. Cytokine. Res.</i> 19:661-669, Mary Ann Liebert, Inc. (1999) | |
| | NPL32 | International Search Report for International Patent Application No. PCT/MX02/00013, European Patent Office, Netherlands, mailed on August 16, 2002 | |
| | NPL33 | Dialog File 351, Accession No. 9271133, Derwent WPI English language abstract for Spanish Patent No. 2 106 183 (Document FP1) | |
| | NPL34 | English language translation of Secretaría de Salud, "Pyrogen Tests," in: <i>Farmacopea de los Estados Unidos Mexicanos</i> , Vol. I, Secretaría de Salud, Mexico City, MX, pp. 334-335 (2000) | |
| | NPL35 | English language translation of Secretaría de Salud, "Potency of Anti-Poison Sera," in <i>Farmacopea de los Estados Unidos Mexicanos</i> , Vol. II, Secretaría de Salud, Mexico City, MX, pp. 1756-1757 (2000) | |
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